

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



INTERNATIONAL BUREAU OF PATENT COOPERATION
35, rue de la Harpe, 1201 Yverdon, Suisse
Tél. (021) 261 1111, Fax (021) 261 1112
E-mail: wipo@wipo.ch

(43) International Publication Date
14 December 2000 (14.12.2000)

PCT

(10) International Publication Number
WO 00/74607 A1

(51) International Patent Classification⁷: **A61F 2/44**

Road, Jackson, NJ 08527 (US). **SCARBOROUGH**, Nelson, L.; 47 Lambert Johnson Drive, Ocean, NJ 07712 (US).

(21) International Application Number: **PCT/US00/15654**

(22) International Filing Date: **8 June 2000 (08.06.2000)**

(25) Filing Language: **English**

(26) Publication Language: **English**

(30) Priority Data:
09/327,982 **8 June 1999 (08.06.1999) US**

(71) Applicant: **OSTEOTECH, INC.** [US/US]; 51 James Way, Eatontown, NJ 07724 (US).

(72) Inventors: **BOYCE, Todd, M.**; 515 Wellington Place, Aberdeen, NJ 07747 (US). **MARTZ, Erik, O.**; 775 Brewers

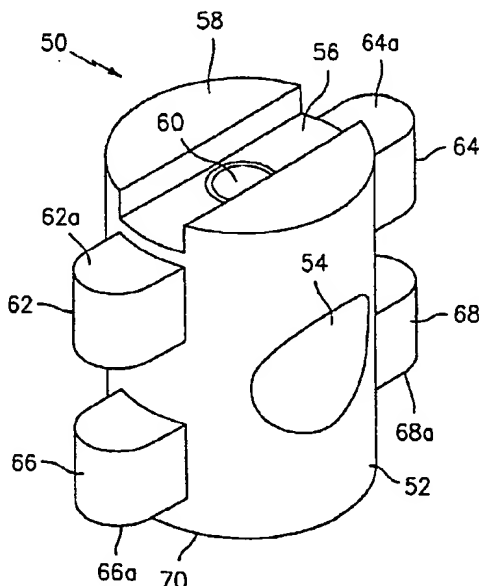
(74) Agents: **DILWORTH, Peter, G. et al.**; Dilworth & Barrese, LLP, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).

(81) Designated States (*national*): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE,

[Continued on next page]

(54) Title: **KEYED INTERVERTEBRAL DOWEL**



(57) Abstract: An intervertebral implant (50) having a tabbed configuration is provided. The intervertebral implant includes a substantially cylindrical body portion (52), and a pair of radially extending tabs (62, 64). The radially extending tabs may be provided as a single or double pair (66, 68), may assume various shapes, and configurations for engaging the interior of a bore (E) formed between adjacent vertebrae (X, Y). A through bore (60) or plurality of through bores extend from the top surface (58) of the implant to the bottom surface (70) of the implant. The implant may be formed from a cortical ring (C) cut from the diaphysis of a long bone (D) by milling. Alternatively, the implant may be formed of any biocompatible material having the requisite strength requirements via any known process, i.e., molding. There is also disclosed a method of insertion of the implant including forming a stepped bore between adjacent vertebrae, inserting the implant between adjacent vertebrae with tabs in alignment with the spaced defined by the adjacent vertebrae, and rotating the implant such that the tabs are rotated within an enlarged or stepped portion of the bore to secure it therein.

WO 00/74607 A1

WO 00/74607 A1

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60 61 62 63 64 65 66 67 68 69 70 71 72 73 74 75 76 77 78 79 80 81 82 83 84 85 86 87 88 89 90 91 92 93 94 95 96 97 98 99 100 101 102 103 104 105 106 107 108 109 110 111 112 113 114 115 116 117 118 119 120 121 122 123 124 125 126 127 128 129 130 131 132 133 134 135 136 137 138 139 140 141 142 143 144 145 146 147 148 149 150 151 152 153 154 155 156 157 158 159 160 161 162 163 164 165 166 167 168 169 170 171 172 173 174 175 176 177 178 179 180 181 182 183 184 185 186 187 188 189 190 191 192 193 194 195 196 197 198 199 200 201 202 203 204 205 206 207 208 209 210 211 212 213 214 215 216 217 218 219 220 221 222 223 224 225 226 227 228 229 230 231 232 233 234 235 236 237 238 239 240 241 242 243 244 245 246 247 248 249 250 251 252 253 254 255 256 257 258 259 260 261 262 263 264 265 266 267 268 269 270 271 272 273 274 275 276 277 278 279 280 281 282 283 284 285 286 287 288 289 290 291 292 293 294 295 296 297 298 299 300 301 302 303 304 305 306 307 308 309 310 311 312 313 314 315 316 317 318 319 320 321 322 323 324 325 326 327 328 329 330 331 332 333 334 335 336 337 338 339 340 341 342 343 344 345 346 347 348 349 350 351 352 353 354 355 356 357 358 359 360 361 362 363 364 365 366 367 368 369 370 371 372 373 374 375 376 377 378 379 380 381 382 383 384 385 386 387 388 389 390 391 392 393 394 395 396 397 398 399 400 401 402 403 404 405 406 407 408 409 410 411 412 413 414 415 416 417 418 419 420 421 422 423 424 425 426 427 428 429 430 431 432 433 434 435 436 437 438 439 440 441 442 443 444 445 446 447 448 449 450 451 452 453 454 455 456 457 458 459 460 461 462 463 464 465 466 467 468 469 470 471 472 473 474 475 476 477 478 479 480 481 482 483 484 485 486 487 488 489 490 491 492 493 494 495 496 497 498 499 500 501 502 503 504 505 506 507 508 509 510 511 512 513 514 515 516 517 518 519 520 521 522 523 524 525 526 527 528 529 530 531 532 533 534 535 536 537 538 539 540 541 542 543 544 545 546 547 548 549 550 551 552 553 554 555 556 557 558 559 560 561 562 563 564 565 566 567 568 569 570 571 572 573 574 575 576 577 578 579 580 581 582 583 584 585 586 587 588 589 590 591 592 593 594 595 596 597 598 599 600 601 602 603 604 605 606 607 608 609 610 611 612 613 614 615 616 617 618 619 620 621 622 623 624 625 626 627 628 629 630 631 632 633 634 635 636 637 638 639 640 641 642 643 644 645 646 647 648 649 650 651 652 653 654 655 656 657 658 659 660 661 662 663 664 665 666 667 668 669 670 671 672 673 674 675 676 677 678 679 680 681 682 683 684 685 686 687 688 689 690 691 692 693 694 695 696 697 698 699 700 701 702 703 704 705 706 707 708 709 710 711 712 713 714 715 716 717 718 719 720 721 722 723 724 725 726 727 728 729 730 731 732 733 734 735 736 737 738 739 740 741 742 743 744 745 746 747 748 749 750 751 752 753 754 755 756 757 758 759 760 761 762 763 764 765 766 767 768 769 770 771 772 773 774 775 776 777 778 779 780 781 782 783 784 785 786 787 788 789 790 791 792 793 794 795 796 797 798 799 800 801 802 803 804 805 806 807 808 809 810 811 812 813 814 815 816 817 818 819 820 821 822 823 824 825 826 827 828 829 830 831 832 833 834 835 836 837 838 839 840 841 842 843 844 845 846 847 848 849 850 851 852 853 854 855 856 857 858 859 860 861 862 863 864 865 866 867 868 869 870 871 872 873 874 875 876 877 878 879 880 881 882 883 884 885 886 887 888 889 890 891 892 893 894 895 896 897 898 899 900 901 902 903 904 905 906 907 908 909 910 911 912 913 914 915 916 917 918 919 920 921 922 923 924 925 926 927 928 929 930 931 932 933 934 935 936 937 938 939 940 941 942 943 944 945 946 947 948 949 950 951 952 953 954 955 956 957 958 959 960 961 962 963 964 965 966 967 968 969 970 971 972 973 974 975 976 977 978 979 980 981 982 983 984 985 986 987 988 989 990 991 992 993 994 995 996 997 998 999 1000 1001 1002 1003 1004 1005 1006 1007 1008 1009 1010 1011 1012 1013 1014 1015 1016 1017 1018 1019 1020 1021 1022 1023 1024 1025 1026 1027 1028 1029 1030 1031 1032 1033 1034 1035 1036 1037 1038 1039 1040 1041 1042 1043 1044 1045 1046 1047 1048 1049 1050 1051 1052 1053 1054 1055 1056 1057 1058 1059 1060 1061 1062 1063 1064 1065 1066 1067 1068 1069 1070 1071 1072 1073 1074 1075 1076 1077 1078 1079 1080 1081 1082 1083 1084 1085 1086 1087 1088 1089 1090 1091 1092 1093 1094 1095 1096 1097 1098 1099 1100 1101 1102 1103 1104 1105 1106 1107 1108 1109 1110 1111 1112 1113 1114 1115 1116 1117 1118 1119 1120 1121 1122 1123 1124 1125 1126 1127 1128 1129 1130 1131 1132 1133 1134 1135 1136 1137 1138 1139 1140 1141 1142 1143 1144 1145 1146 1147 1148 1149 1150 1151 1152 1153 1154 1155 1156 1157 1158 1159 1160 1161 1162 1163 1164 1165 1166 1167 1168 1169 1170 1171 1172 1173 1174 1175 1176 1177 1178 1179 1180 1181 1182 1183 1184 1185 1186 1187 1188 1189 1190 1191 1192 1193 1194 1195 1196 1197 1198 1199 1200 1201 1202 1203 1204 1205 1206 1207 1208 1209 1210 1211 1212 1213 1214 1215 1216 1217 1218 1219 1220 1221 1222 1223 1224 1225 1226 1227 1228 1229 1230 1231 1232 1233 1234 1235 1236 1237 1238 1239 1240 1241 1242 1243 1244 1245 1246 1247 1248 1249 1250 1251 1252 1253 1254 1255 1256 1257 1258 1259 1260 1261 1262 1263 1264 1265 1266 1267 1268 1269 1270 1271 1272 1273 1274 1275 1276 1277 1278 1279 1280 1281 1282 1283 1284 1285 1286 1287 1288 1289 1290 1291 1292 1293 1294 1295 1296 1297 1298 1299 1300 1301 1302 1303 1304 1305 1306 1307 1308 1309 1310 1311 1312 1313 1314 1315 1316 1317 1318 1319 1320 1321 1322 1323 1324 1325 1326 1327 1328 1329 1330 1331 1332 1333 1334 1335 1336 1337 1338 1339 1340 1341 1342 1343 1344 1345 1346 1347 1348 1349 1350 1351 1352 1353 1354 1355 1356 1357 1358 1359 1360 1361 1362 1363 1364 1365 1366 1367 1368 1369 1370 1371 1372 1373 1374 1375 1376 1377 1378 1379 1380 1381 1382 1383 1384 1385 1386 1387 1388 1389 1390 1391 1392 1393 1394 1395 1396 1397 1398 1399 1400 1401 1402 1403 1404 1405 1406 1407 1408 1409 1410 1411 1412 1413 1414 1415 1416 1417 1418 1419 1420 1421 1422 1423 1424 1425 1426 1427 1428 1429 1430 1431 1432 1433 1434 1435 1436 1437 1438 1439 1440 1441 1442 1443 1444 1445 1446 1447 1448 1449 1450 1451 1452 1453 1454 1455 1456 1457 1458 1459 1460 1461 1462 1463 1464 1465 1466 1467 1468 1469 1470 1471 1472 1473 1474 1475 1476 1477 1478 1479 1480 1481 1482 1483 1484 1485 1486 1487 1488 1489 1490 1491 1492 1493 1494 1495 1496 1497 1498 1499 1500 1501 1502 1503 1504 1505 1506 1507 1508 1509 1510 1511 1512 1513 1514 1515 1516 1517 1518 1519 1520 1521 1522 1523 1524 1525 1526 1527 1528 1529 1530 1531 1532 1533 1534 1535 1536 1537 1538 1539 1540 1541 1542 1543 1544 1545 1546 1547 1548 1549 1550 1551 1552 1553 1554 1555 1556 1557 1558 1559 1560 1561 1562 1563 1564 1565 1566 1567 1568 1569 1570 1571 1572 1573 1574 1575 1576 1577 1578 1579 1580 1581 1582 1583 1584 1585 1586 1587 1588 1589 1590 1591 1592 1593 1594 1595 1596 1597 1598 1599 1600 1601 1602 1603 1604 1605 1606 1607 1608 1609 1610 1611 1612 1613 1614 1615 1616 1617 1618 1619 1620 1621 1622 1623 1624 1625 1626 1627 1628 1629 1630 1631 1632 1633 1634 1635 1636 1637 1638 1639 1640 1641 1642 1643 1644 1645 1646 1647 1648 1649 1650 1651 1652 1653 1654 1655 1656 1657 1658 1659 1660 1661 1662 1663 1664 1665 1666 1667 1668 1669 1670 1671 1672 1673 1674 1675 1676 1677 1678 1679 1680 1681 1682 1683 1684 1685 1686 1687 1688 1689 1690 1691 1692 1693 1694 1695 1696 1697 1698 1699 1700 1701 1702 1703 1704 1705 1706 1707 1708 1709 1710 1711 1712 1713 1714 1715 1716 1717 1718 1719 1720 1721 1722 1723 1724 1725 1726 1727 1728 1729 1730 1731 1732 1733 1734 1735 1736 1737 1738 1739 1740 1741 1742 1743 1744 1745 1746 1747 1748 1749 1750 1751 1752 1753 1754 1755 1756 1757 1758 1759 1760 1761 1762 1763 1764 1765 1766 1767 1768 1769 1770 1771 1772 1773 1774 1775 1776 1777 1778 1779 1780 1781 1782 1783 1784 1785 1786 1787 1788 1789 1790 1791 1792 1793 1794 1795 1796 1797 1798 1799 1800 1801 1802 1803 1804 1805 1806 1807 1808 1809 1810 1811 1812 1813 1814 1815 1816 1817 1818 1819 1820 1821 1822 1823 1824 1825 1826 1827 1828 1829 1830 1831 1832 1833 1834 1835 1836 1837 1838 1839 1840 1841 1842 1843 1844 1845 1846 1847 1848 1849 1850 1851 1852 1853 1854 1855 1856 1857 1858 1859 1860 1861 1862 1863 1864 1865 1866 1867 1868 1869 1870 1871 1872 1873 1874 1875 1876 1877 1878 1879 1880 1881 1882 1883 1884 1885 1886 1887 1888 1889 1890 1891 1892 1893 1894 1895 1896 1897 1898 1899 1900 1901 1902 1903 1904 1905 1906 1907 1908 1909 1910 1911 1912 1913 1914 1915 1916 1917 1918 1919 1920 1921 1922 1923 1924 1925 1926 1927 1928 1929 1930 1931 1932 1933 1934 1935 1936 1937 1938 1939 1940 1941 1942 1943 1944 1945 1946 1947 1948 1949 1950 1951 1952 1953 1954 1955 1956 1957 1958 1959 1960 1961 1962 1963 1964 1965 1966 1967 1968 1969 1970 1971 1972 1973 1974 1975 1976 1977 1978 1979 1980 1981 1982 1983 1984 1985 1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033 2034 2035 2036 2037 2038 2039 2040 2041 2042 2043 2044 2045 2046 2047 2048 2049 2050 2051 2052 2053 2054 2055 2056 2057 2058 2059 2060 2061 2062 2063 2064 2065 2066 2067 2068 2069 2070 2071 2072 2073 2074 2075 2076 2077 2078 2079 2080 2081 2082 2083 2084 2085 2086 2087 2088 2089 2090 2091 2092 2093 2094 2095 2096 2097 2098 2099 2100 2101 2102 2103 2104 2105 2106 2107 2108 2109 2110 2111 2112 2113 2114 2115 2116 2117 2118 2119 2120 2121 2122 2123 2124 2125 2126 2127 2128 2129 2130 2131 2132 2133 2134 2135 2136 2137 2138 2139 2140 2141 2142 2143 2144 2145 2146 2147 2148 2149 2150 2151 2152 2153 2154 2155 2156 2157 2158 2159 2160 2161 2162 2163 2164 2165 2166 2167 2168 2169 2170 2171 2172 2173 2174 2175 2176 2177 2178 2179 2180 2181 2182 2183 2184 2185 2186 2187 2188 2189 2190 2191 2192 2193 2194 2195 2196 2197 2198 2199 2200 2201 2202 2203 2204 2205 2206 2207 2208 2209 2210 2211 2212 2213 2214 2215 2216 2217 2218 2219 2220 2221 2222 2223 2224 2225 2226 2227 2228 2229 2230 2231 2232 2233 2234 2235 2236 2237 2238 2239 2240 2241 2242 2243 2244 2245 2246 2247 2248 2249 2250 2251 2252 2253 2254 2255 2256 2257 2258 2259 2260 2261 2262 2263 2264 2265 2266 2267 2268 2269 2270 2271 2272 2273 2274 2275 2276 2277 2278 2279 2280 2281 2282 2283 2284 2285 2286 2287 2288 2289 2290 2291 2292 2293 2294 2295 2296 2297 2298 2299 2300 2301 2302 2303 2304 2305 2306 2307 2308 2309 2310 2311 2312 2313 2314 2315 2316 2317 2318 2319 2320 2321 2322 2323 2324 2325 2326 2327 2328 2329 2330 2331 2332 2333 2334 2335 2336 2337 2338 2339 2340 2341 2342 2343 2344 2345 2346 2347 2348 2349 2350 2351 2352 2353 2354 2355 2356 2357 2358 2359 2360 2361 2362 2363 2364 2365 2366 2367 2368 2369 2370 2371 2372 2373 2374 2375 2376 2377 2378 2379 2380 2381 2382 2383 2384 2385 2386 2387 2388 2389 2390 2391 2392 2393 2394 2395 2396 2397 2398 2399 2400 2401 2402 2403 2404 2405 2406 2407 2408 2409 2410 2411 2412 2413 2414 2415 2416 2417 2418 2419 2420 2421 2422 2423 2424 2425 2426 2427 2428 2429 2430 2431 2432 2433 2434 2435 2436 2437 2438 2439 2440 2441 2442 2443 2444 2445 2446 2447 2448 2449 2450 2451 2452 2453 2454 2455 2456 2457 2458 2459 2460 2461 2462 2463 2464 2465 2466 2467 2468 2469 2470 2471 2472 2473 2474 2475 2476 2477 2478 2479 2480 2481 2482 2483 2484 2485 2486 2487 2488 2489 2490 2491 2492 2493 2494 2495 2496 2497 2498 2499 2500 2501 2502 2503 2504 2505 2506 2507 2508 2509 2510 2511 2512 2513 2514 2515 2516 2517 2518 2519 2520 2521 2522 2523 2524 2525 2526 2527 2528 2529 2530 2531 2532 2533 2534 2535 2536 2537 2538 2539 2540 2541 2542 2543 2544 2545 2546 2547 2548 2549 2550 2551 2552 2553 2554 2555 2556 2557 2558 2559 2560 2561 2562 2563 2564 2565 2566 2567 2568 2569 2570 2571 2572 2573 2574 2575 2576 2577 2578 2579 2580 2581 2582 2583 2584 2585 2586 2587 2588 2589 2590 2591 2592 2593 2594 2595 2596 2597 2598 2599 2600 2601 2602 2603 2604 2605 2606 2607 2608 2609 2610 2611 2612 2613 2614 2615 2616 2617 2618 2619 2620 2621 2622 2623 2624 2625 2626 2627 2628 2629 2630 2631 2632 2633 2634 2635 2636 2637 2638 2639 2640 2641 2642 2643 2644 2645 2646 2647 2648 2649 2650 2651 2652 2653 2654 2655 2656 2657 2658 2659 2660 2661 2662 2663 2664 2665 2666 2667 2668 2669 2670 2671 2672 2673 2674 2675 2676 2677 2678 2679 2680 2681 2682 2683

Description

5

10

15

20

25

30

35

40

45

50

55

5

KEYED INTERVERTEBRAL DOWEL

10

5 BACKGROUND OF THE INVENTION1. Technical Field

15

The present disclosure relates to an intervertebral implant for spinal fusion and more particularly, to an intervertebral dowel having at least two radially extending tabs for securing the dowel within a receiving bed formed in the intervertebral space.

20

10

2. Background of Related Art

25

The spine is a flexible column formed of a series of bone called vertebrae. The vertebrae are hollow and piled one upon the other, forming a strong hollow column for support of the cranium and trunk. The hollow core of the spine houses and protects the nerves of the spinal cord. The different vertebrae are connected together by means of articular processes and intervertebral, fibro-cartilages. In general, a vertebral body is made of a cortical shell enclosing a cancellous (spongy) bone core. The portion of the cortical bone shell facing the surface of the disk is the endplate.

30

15

35

40

20

The intervertebral fibro-cartilages are also known as intervertebral disks and are made of a fibrous ring filled with pulpy material. The disks function as spinal shock absorbers and also cooperate with synovial joints to facilitate movement and maintain flexibility of the spine. When one or more disks degenerate through trauma,

45

50

55

5

10

spondylolisthesis or other pathologies, nerves passing near the affected area may be compressed and are consequently irritated. The result may be chronic and/or debilitating back pain. Various methods and apparatus, both surgical and non-surgical, have been designed to relieve such back pain.

15

5

20

10

25

One method designed to relieve such back pain is interbody spinal fusion. Typically, interbody spinal fusion involves distracting adjoining vertebrae of the spine so that the nerve root canal sizes are increased and nerve irritation is eliminated or reduced. In order to maintain the adjoining vertebrae in a distracted state, at least one intervertebral implant is inserted into a receiving bed formed between the vertebrae. The implant is positioned to engage the adjoining vertebrae to maintain the vertebrae at a fixed degree of distraction.

30

15

35

40

20

45

Preferably, the implant should stabilize the intervertebral space and become fused to adjacent vertebrae in order to prevent the implant and adjacent vertebrae from moving. The implant must also provide spinal load support between the vertebrae. Further, during the time it takes for fusion, i.e. biological fixation of the vertebrae, to be completed, the implant should have enough structural integrity to maintain the space without substantial degradation or deformation of the implant. The implant should also have sufficient stability to remain in place prior to actual completion of bone ingrowth fusion. The implant should include structure which maintains the implant in position between the vertebrae while bone ingrowth is occurring. To facilitate rapid bone growth, and thus quick fusion, the implant may

50

55

5

10

include or be provided with a bone growth supporting material. Obviously, the material from which the implant is constructed should be a biocompatible material and, preferably, interact biologically with the body's own naturally occurring tissues.

15

20

A variety of different types of intervertebral implants have been developed to perform this function including spinal fusion cages, threaded bone dowels and stepped bone dowels. An exemplary implant is disclosed in U.S. Patent Application filed on even date herewith, under Certificate of Express Mail Label No. EL260888076US, and entitled "Ramp-Shaped Intervertebral Implant", the entire disclosure of which is incorporated by reference herein.

25

30

10 Common deficiencies in some of the prior art implants may include expulsion of the implant from between adjacent vertebrae, difficulty in inserting the implant into position, and/or lack of ability to allow incorporation of implant into the body. Also, in some prior art spinal fusion methods utilizing implants, the vertebrae may need to be distracted to a large extent in order to position the implant between the vertebrae.

35

40

45

Accordingly, a need exists for an improved intervertebral implant which is configured to prevent the likelihood of expulsion or retropulsion during normal patient activity, provide ease of insertion and include structure to facilitate incorporation of the implant into the body. Furthermore, need exists for an improved intervertebral implant which can be inserted between vertebrae without excessive distraction of the vertebrae and a method of installing such an implant.

50

55

5

SUMMARY

10

In accordance with the present disclosure, an intervertebral implant having tabbed securing structure is provided. The intervertebral implant includes a substantially cylindrical body portion and at least one pair of radially extending tabs that are configured to engage vertebral bodies.

15

By engaging the vertebrae, the tabs reduce the likelihood that expulsion or retropulsion might occur. This is particularly significant in that where an implant is pushed out of place, damage to vital structures including neural (the spinal cord and existing nerve roots) and vascular (the aorta and inferior vena cava) can occur resulting in possible injury or death. Additionally, the tabs assist in preventing migration of the implant due to rotation of the adjacent vertebrae.

25

30

The tabs may take the form of various shape and constructions, such as, for example, smooth rounded, wedge shaped, cam shaped, toothed, or threaded, etc. In alternate embodiments, two diametrically opposed pairs of tabs are provided on the cylindrical body portion. In various embodiments, a throughbore or a plurality of throughbores extend from a top surface of the implant to the bottom surface of the implant providing a space for boney bridging to occur between the vertebrae which are intended to be fused. The throughbore(s) is dimensioned to receive growth factors or other grafting materials to stimulate bone healing. The pairs of tabs may be provided adjacent the opening of the throughbore or may be offset 90° from the openings of the throughbore. In one embodiment of an intervertebral implant, the cylindrical body portion is tapered.

40

45

50

55

5

In an alternate embodiment, the implant has an abbreviated body portion and does not include a throughbore.

10

In another embodiment, the tabs are formed by inserting a cortical plug through the throughbore. Preferably, the cylindrical body portion includes a slot
5 formed in one end thereof for receipt of an insertion tool and a bore extending between the slot and into the throughbore for facilitating insertion and facilitating injection into the throughbore of any desirable material, such as, for example, bone growth
15 stimulants, autograft, allograft, demineralized bone matrix, or other bone grafting materials.

20

25

10 Further, alternate embodiments may include body portions having shapes other than cylindrical, such as, those having rectangular, oval, multi-sided, etc., cross-sections.

30

In a preferred embodiment, the implant is formed from a cortical ring allograft cut from the diaphysis of a long bone. By utilizing bone or bone-derived
15 materials as the implant material, the implant has the added advantage of facilitating incorporation of the implant into the body. The implant can be formed by milling the top and bottom surfaces of a cortical ring to form the substantially cylindrical body
35 portion and a pair of radially extending wings. The implant is further milled such that the radially extending wings are formed into tabs each of which is spaced a
40 predetermined distance from the end of the cylindrical body portion. Additionally,
20 each tab may be milled so as to form the desired camming, wedge, threaded, etc.

45

50

55

5

10

15

20

25

30

35

40

45

50

55

shape. The implant is milled such that the intramedullary canal of the cortical ring defines a throughbore in the cylindrical body portion of the implant. Alternatively, the implant may be formed of any biocompatible material such as titanium and titanium alloys, stainless steel, carbon fiber, ceramics, etc. having the requisite strength requirements via any known process, i.e., molding, machining, etc. Further, it is preferable that the implants be surface demineralized prior to use by exposing them to acid or other demineralizing solutions.

Preferably, the bone should be surface demineralized prior to use.

Where partially or surface demineralized bone is utilized, such bone can be obtained employing known demineralization techniques, e.g., those employing strong acids such as hydrochloric acid as described in Reddi et al., Proc. Nat. Acad. Sci. 69, pp. 1601-1605 (1972), the entire disclosure of which is incorporated herein by reference. The extent of demineralization is a function of the strength of the acid solution, the shape of the bone and the duration of the demineralization treatment as disclosed in Lewandrowski et al., J. Biomed. Materials Res., 31, pp. 365-372 (1996) the disclosure of which is incorporated by reference herein. The use of partially or surface demineralized bone is beneficial since such substances exhibit greater initial osteogenic and/or osteoinductive activity than fully mineralized bone.

There is also disclosed a method of inserting the tabbed implant between adjacent vertebrae. The method involves forming a stepped bore between adjacent vertebrae, providing an intervertebral implant having a cylindrical body portion and at

5 least one pair of diametrically opposite radially extending tabs extending from the
cylindrical body portion and inserting the implant between adjacent vertebrae such that
10 the tabs are in alignment with the space defined between adjacent vertebrae. The
method further includes positioning the implant such that the tabs are within the
5 enlarged areas of the stepped bore and rotating the implant such that the tabs enter the
15 enlarged or stepped area of the bore. This provides a greater ease of insertion over
other styles of implants, such as, for example, threaded implants.

20 BRIEF DESCRIPTION OF THE DRAWINGS

Various preferred embodiments are described herein with reference to
10 the drawings wherein:

25 FIG. 1 is a perspective view of one embodiment of the presently
disclosed intervertebral implant;

30 FIG. 2 is a side view of the intervertebral implant shown in FIG. 1;

FIG. 3 is a top view of the intervertebral implant shown in FIG. 1;

15 FIG. 4 is a front view of the intervertebral implant shown in FIG. 1;

35 FIG. 5 is a side view of a long bone;

FIG. 6 is a perspective view of a ring cut from the long bone shown in

40 FIG. 5;

FIG. 7 is a side view of the ring shown in FIG. 6;

20 FIG. 8 is a perspective view of the ring after the top surface has been
45 milled;

5

FIG. 9 is a perspective view of the ring after the bottom surface has been milled;

10

FIG. 10 is a perspective view of the ring after the side walls have been machined;

15

5 FIG. 11 is a perspective view of the ring after the radially extending wings have been machined to form tabs;

20

FIG. 12 is a an end view of the vertebral space with a stepped hole drilled therein;

25

10 FIG. 13 is a side view of the vertebral space shown in FIG. 12;
FIG. 14 is an end view of the vertebral space of FIG. 12 with one embodiment of the presently disclosed intervertebral implant inserted therein;

30

FIG. 15 is a perspective view similar to FIG. 14 with the intervertebral implant rotated 90°;

35

15 FIG. 16 is a side view of the intervertebral space similar to FIG. 13 with the intervertebral implant inserted and rotated 90°;

40

FIG. 17 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

45

FIG. 18 is a side view of the intervertebral implant shown in FIG. 17;
FIG. 19 is a top view of the intervertebral implant shown in FIG. 17;
20 FIG. 20 is a front view of the intervertebral implant shown in FIG. 17;

50

55

5

FIG. 21 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

10

FIG. 22 is a side view of the intervertebral implant shown in FIG. 21;

FIG. 23 is a top view of the intervertebral implant shown in FIG. 21;

15

5

FIG. 24 is a front view of the intervertebral implant shown in FIG. 21;

FIG. 25 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

20

FIG. 26 is a side view of the intervertebral implant shown in FIG. 25;

FIG. 27 is a top view of the intervertebral implant shown in FIG. 25;

25

10

FIG. 28 is a front view of the intervertebral implant shown in FIG. 25;

FIG. 29 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

30

FIG. 30 is a side view of intervertebral implant shown in FIG. 29;

FIG. 31 is a top view of the intervertebral implant shown in FIG. 29;

35

15

FIG. 32 is a front view of the intervertebral implant shown in FIG. 29;

FIG. 33 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

40

FIG. 34 is a side view of the intervertebral implant shown in FIG. 33;

FIG. 35 is a top view of the intervertebral implant shown in FIG. 33;

45

20

FIG. 36 is a front view of the intervertebral implant shown in FIG. 33;

50

55

5

FIG. 37 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

10

FIG. 38 is a side view of the intervertebral implant shown in FIG. 37;

FIG. 39 is top view of the intervertebral implant shown in FIG. 37;

15

5

FIG. 40 is a front view of the intervertebral implant shown in FIG. 37;

FIG. 41 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

20

FIG. 42 is a side view of the intervertebral implant shown in FIG. 41;

FIG. 43 is a top view of the intervertebral implant shown in FIG. 41;

25

10

FIG. 44 is a front view of the intervertebral implant shown in FIG. 41;

FIG. 45 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

30

FIG. 46 is a side view of the intervertebral implant shown in FIG. 45;

FIG. 47 is a top view of the intervertebral implant shown in FIG. 45;

35

15

FIG. 48 is a front view of the intervertebral implant shown in FIG. 45;

FIG. 49 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

40

FIG. 50 is a side view of the intervertebral implant shown in FIG. 49;

FIG. 51 is a top view of the intervertebral implant shown in FIG. 49;

45

50

55

5

FIG. 52 is a front view of the intervertebral implant shown in FIG. 49;

10

FIG. 53 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

15

5

FIG. 54 is a side view of the intervertebral implant shown in FIG. 53;

FIG. 55 is a top view of the intervertebral implant shown in FIG. 53;

FIG. 56 is a front view of the intervertebral implant shown in FIG. 53;

20

FIG. 57 is a perspective view of another embodiment of the presently disclosed intervertebral implant;

25

10

FIG. 58 is a side view of the intervertebral implant shown in FIG. 57;

FIG. 59 is a top view of the intervertebral implant shown in FIG. 57;

FIG. 60 is a front view of the intervertebral implant shown in FIG. 57;

30

FIG. 61 is a perspective view of another embodiment of the presently disclosed intervertebral implant body portion with a rectangular cross-section;

35

15

FIG. 62 is a perspective view of another embodiment of the presently disclosed intervertebral implant body portion with an oval cross-section; and

FIG. 63 is a perspective view of another embodiment of the presently

disclosed intervertebral implant body portion with a multi-sided cross-section.

40

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

45

Preferred embodiments of the presently disclosed intervertebral implant will now be described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views.

50

55

5

10

15

20

25

The spinal interbody fusion devices or intervertebral implants according to the present disclosure are intended to be placed between adjacent vertebrae in an attempt to correct a debilitating degeneration of the spinal structure. In humans, the device may be used predominantly in the lumbar region of the spine, but is adjustable for use in the thoracic and cervical regions as well. When in place, the device supports and maintains an appropriate distance between vertebrae and causes bone tissue to form and become integral with the device. Consequently, the intervertebral space becomes filled with autologous bone tissue and forms an integral rigid bone construction between adjacent vertebrae. While the disclosed implants and methods are discussed in terms of humans, it is contemplated that the disclosed implants and methods may find beneficial use in veterinary applications.

30

35

The disclosed intervertebral implants are formed with a tabbed configuration which allows the implants to be inserted between the vertebrae and twisted or rotated to secure the implant in position between the vertebrae. This has the resultant benefits of reduced likelihood of expulsion. Furthermore, the implants disclosed herein also allow insertion of the implant between the vertebral space without excessive distraction between the vertebrae.

40

45

Referring now to FIGS. 1-4, there is illustrated one embodiment of the presently disclosed intervertebral implant shown generally as 10. Briefly, intervertebral implant 10 includes a substantially cylindrical body portion 12 having a pair of diametrically opposed and radially extending tabs 14 and 16. Cylindrical body

50

55

5 portion 12 has a first end 18 and a second end 20. Tab 14 has first and second
engaging or retaining surfaces 22a and 22b which are stepped or longitudinally spaced
10 a predetermined distance from first end 18 and second end 20, respectively. Similarly,
tab 16 has a pair of retaining surfaces 24a and 24b which are similarly stepped or
5 longitudinally spaced from a first end 18 and second end 20 respectively. Retaining
15 surfaces 22a, 22b and 24a, 24b are configured to engage a portion of adjacent vertebrae
when installed therebetween.

20 As shown, tabs 14 and 16 extend only along a limited extent of the
circumference of a cylindrical body portion 12. Preferably, tabs 14 and 16 are radially
10 spaced 180° apart. Tab 14 includes a rounded side surface 26 and tab 16 includes a
25 rounded side surface 28.

As shown, implant 10 includes a throughbore 30 which has a
30 longitudinal axis substantially perpendicular to the longitudinal axis of implant 10.
Further, implant 10 may be provided with perforations instead of, or in addition to,
15 throughbore 30. Where implant 10 is formed of bone, the perforations assist in
35 facilitating biological attachment and eventual incorporation of the implant into adjacent
vertebrae.

40 Implant 10 further includes an installation slot 32 machined or milled in
first end 18. A second bore 34 extends between slot 32 and throughbore 30. Second
20 bore 34 is provided for mating of the implant with an insertion tool. Throughbore 30
45 is dimensioned to receive bone particles and/or biocompatible osteoinductive or

5

osteochonductive material. These materials may include cancellous bone, cancellous bone particles, ceramics, polymers, composites, BMP, etc.

10

15

20

25

30

35

40

45

50

55

Intervertebral implant 10 can be constructed from a broad range of biocompatible materials such as, for example, surgical stainless steel, titanium, ceramic, hydroxyapatite, polymer, carbon fiber, tantalum, etc. Preferably, implant 10 is constructed from a human and/or animal cadaver bone. Intervertebral implant 10, appropriately sized, can be used in cervical, thoracic and lumbar spinal fusion procedures. For cervical spinal fusion procedures, in which implants are typically between 8 to 15 mm in length and 10 to 14 mm in diameter, bone is preferably obtained from the fibula, radius, ulna or humerus bones. For thoracic and lumbar spinal fusion procedures in which implants are typically 10 to 30 mm in length and/or diameter and about 10 to 14 mm in height, bone is preferably obtained from the humerus, femur or tibia. The sources of cortical bone for the bone-derived implant are preferably allogenic but also include xenogenic sources such as bovine and porcine bone.

Additionally, the bone may be subjected to penetration with osteogenic or demineralization agents during manufacture of the implant.

Alternatively, as discussed above, intervertebral implant 10 can be molded or machined from other biocompatible materials including composites made of bone as discussed in U.S. Patent No. 5,899,939 to Boyce et al., the entire disclosure of which is incorporated by reference herein.

5

10

15

20

25

30

35

40

45

50

55

Referring now to Figs. 5-11, in one preferred embodiment, intervertebral implant 10 is manufactured in accordance with the procedure disclosed in U.S. Patent Application filed on even date herewith under Certificate of Express Mail Label No. EL260888080US and entitled, "Intervertebral Implant", the entire disclosure of which is incorporated by reference herein. In general, implant 10 is manufactured from a ring C formed by making transverse cuts through a long bone D along lines A and B as illustrated in FIG. 5. Next, the top 36 of ring C is machined using a milling device (not shown) having a dome or crown configuration to shape one side of ring C to have a semi-cylindrical portion 38 with two radially extending flats 40 (Fig. 8). Ring C is flipped over and the same milling procedure is formed on a bottom 42 of ring C as shown in Fig. 9. Next, the front and side surfaces are machined to flatten the side surface to reconfigure femoral ring C to have a generally rectangular configuration (Fig. 10). Finally, tabs 14 and 16 are formed by machine flats 40 so as to provide stepped surfaces from first and second ends 18 and 20 (Fig. 11). Additionally, further milling may be performed to provide rounded side surfaces 26 and 28 on tabs 14 and 16 respectively. It should be noted that throughbore 30 may be formed from a medullary canal through the long bone and further milled to provide a uniform throughbore 30 through ring C. While not shown, first end 18 may be further milled and/or drilled to provide installation slot 32 and bore 34 extending between installation slot 32 and an interior of throughbore 30. As discussed above, intervertebral implant 10 need not be formed from cadaveric bone but rather may be formed from any

5 biocompatible material. As such, other known processes, such as molding techniques may be used to manufacture the implant.

10 Installation of implant 10 between a pair of adjacent vertebrae will now be described. Referring to Figs. 12-16 and initially to Figs. 12-13, there is illustrated
5 a pair of adjacent vertebrae X and Y defining intervertebral space Z therebetween. The
15 endplate is stronger bone than is the cancellous core. Thus, cuts in the vertebral bodies permit the tabs of the implant to extend past the endplate and into the softer bone
20 beneath. A camming approach for some of the following disclosed embodiments of the implant tabs allows the cancellous bone to be compressed against the implant thereby
10 providing additional frictional resistance against implant movement. A drill or other
25 known devices and methods are utilized to form a stepped hole or bore E between the adjacent vertebrae preferably by milling or machining. Examples of such devices and
30 procedures are disclosed in U.S. Patent No. 5,445,639, the entire disclosure of which is incorporated by reference herein. Stepped hole E preferably has narrow diameter
15 portion F adjacent the outer surface of the vertebrae and enlarged portion G interior to the vertebrae. In preparation for use, intervertebral implant 10 may be demineralized
35 as discussed hereinabove and mounted on suitable installation devices.

40 Referring now to Fig. 14, once installed on an insertion device, intervertebral implant 10 is inserted between vertebrae X and Y such that tabs 14 and
20 16 are aligned with the intervertebral space Z. Intervertebral implant 10 is inserted
45 into the drilled hole a sufficient distance such that tabs 14 and 16 align with the

5

10

15

20

25

30

35

40

45

50

55

enlarged portion G of bore E. Implant 10 is subsequently rotated approximately 90° such that tabs 14 and 16 rotate into enlarged portion G. As noted above, retaining surfaces 22a and 22b on tab 14 and retaining surfaces 24a and 24b on tab 16 engage edges of enlarged portion G of bore E and prevent expulsion of the implant from between the adjacent vertebrae A and B. It should be noted that the entire procedure may be accomplished without any substantial or excessive distraction between adjacent vertebrae. While the present disclosure provides installation slot 37 and bore 32 for receipt of an installation device, it is within the contemplated scope of the present disclosure to provide implant 10 with other structure to allow insertion and rotation of the implant by various insertion tools.

Referring now to FIGS. 17-19, there is disclosed an alternative embodiment of an intervertebral implant. Intervertebral implant 50 is similar to implant 10 described above and generally includes cylindrical body portion 52 having a throughbore 54 formed therein. An installation slot 56 is provided in a first end 58 and a bore 60 extends from slot 56 to the interior of throughbore 54 similar to that described above with respect to implant 10.

Implant 50 includes a pair of radially extending first tabs 62 and 64 adjacent to, and longitudinally displaced from, first end 58 and a pair of second tabs 66 and 68 adjacent to, and longitudinally spaced from, a second end 70 of cylindrical body portion 52. Thus, first tabs 62 and 64 as well as second tabs 66 and 68 are stepped from first and second ends 58 and 70 respectively. First tabs 62 and 64 include

5

10

15

engaging surfaces 62a and 64a for engaging an edge of stepped bore in a drilled vertebrae. Similarly, second tabs 66 and 68 also include engaging surfaces 66a and 68a for engaging an interior of a bore drilled in bone or vertebrae. Similar to that disclosed with regard to implant 10, first tabs 62 and 64 as well as second tabs 66 and 68 may have a generally rounded profile.

20

25

Intervertebral implant 50 is formed in the manner disclosed above with respect to implant 10 and is similarly installed in a stepped bore drilled in adjacent vertebrae. The stepped bore may have only a single enlarged area or may include two separate enlarged areas to accommodate the first and second tabs as the intervertebral implant is rotated into place.

30

35

40

Referring now to FIGS. 21-24, there is disclosed another alternate embodiment of an intervertebral implant similar to that of implant 50. Intervertebral implant 80 includes a generally cylindrical body portion 82 having a throughbore 84 formed therethrough. An installation slot 86 is provided along with a bore 88 extending between installation slot 86 and an interior of throughbore 84. Implant 80 includes a pair of radially extending first tabs 90 and 92 as well as a pair of radially extending second tabs 94, 96. In contrast to implant 50, first tabs 90, 92 and second tabs 94, 96 are formed on cylindrical body portion such that they are generally perpendicular to slot 86 and are adjacent to throughbore 84.

45

In the presently disclosed embodiments where the tabs are adjacent to the throughbore, a different method of forming the implant from bone is necessary.

50

55

5

10

15

The bone will initially be cut parallel to the long axis of the long bone to permit the tabs to extend in a plane that transects the medullary canal. Subsequently, the presently disclosed methods of milling or machining the bone are performed to form the body portion and tabs. An installation shaft and bore between the installation slot and throughbore may be formed.

20

25

30

35

40

Referring now to FIGS. 25-28, there is disclosed another embodiment of an intervertebral implant which includes specific wedging structure to prevent the implant from moving longitudinally within a bore. Implant 100 generally includes a cylindrical body portion 102 having a throughbore 104 formed therein. Similar to previous embodiments, implant 100 is provided with an installation slot 106 and a bore 108 extending between installation slot 106 and throughbore 104. Implant 100 also includes a pair of radially extending first anterior tabs 110, 112 and a pair of radially extending second tabs 114, 116. As shown, first tabs 110 and 112 have curved wedge surfaces 118, 120. Similarly, second tabs 114 and 116 also include curved wedge surfaces 122 and 124. Wedge surfaces 118 and 120 of first tabs 110 and 112 curve away from a first end 126 of implant 100 and wedge surfaces 122, 124 of second tabs 114 and 116 curve away from a second end 128 of implant 100. The provision of wedge surfaces on the tabs provides a range of camming contact with the interior of a stepped bore drilled in adjacent vertebrae to thereby prevent expulsion of the implant.

20

45

Referring now to FIGS. 29-32, there is disclosed a further alternate embodiment of an intervertebral implant which includes progressive, radial camming

50

55

5 structure which, upon rotation of the implant, cams the implant into position within a stepped bore. Specifically, intervertebral implant 130 includes a cylindrical body
10 portion 132 having a throughbore 34 formed therethrough. An installation slot 136 may be provided along with a bore 138 extending between installation slot 136 and
5 throughbore 134. Implant 130 additionally includes first tabs 140 and 142 formed
15 adjacent first end 144 and second tabs 146 and 148 formed adjacent a second end 150. As illustrated, first tabs 140 and 142 as well as second tabs 146 and 148 have a
20 generally, progressively curved shape such as a spline shape or one defined by a polynomial-defined curve. Thus, first tabs 140, 142 include progressive camming
10 surfaces 152, 154. Second tabs 146 and 148 include progressive camming surfaces 156
25 and 158. Implant 130 may be formed in a manner similarly described above with respect to implant 10.

30 Upon installation of implant 130, between adjacent vertebrae, implant 130 is rotated and progressive camming surfaces 152, 154 and 156, 158 engage walls
15 of the stepped bore in progressive fashion to firmly wedge implant 130 within the stepped bore and prevent any loosening or further rotation or reverse rotation of
35 implant 130 within the stepped bore. The provision of progressive camming surfaces allows for the use of implant 130 in bores which may not have been drilled precisely or
40 to a constant/consistent diameter. Further, as noted above, camming structure on the disclosed implants allows the tabs to compress the spongy bone to gain additional
20 frictional force to secure the implant between the vertebrae.
45

5

10

15

20

25

30

35

40

45

50

55

Referring now to FIGS. 33-36, there is disclosed another alternate embodiment of an intervertebral implant including camming surfaces provided on tabs so as to allow the implant to be cammed within a stepped bore formed in adjacent vertebrae upon rotation of the implant. Specifically, implant 160 includes a cylindrical body portion having a throughbore 164 and installation slot 166 and a bore 168 extending between installation slot 166 and throughbore 164. A pair of radially extending first tabs 170, 172 and a pair of radially extending second tabs 174, 176 are formed on cylindrical body portion 162. First tabs 170 and 172 have relatively flat camming surfaces 178 and 180, respectively, formed thereon, while second tabs 174, 176 also include relatively flat camming surfaces 182, 184, respectively, formed thereon. As with implant 130, rotation of implant 160 within a stepped bore causes the camming surfaces 178, 180 and 182, 184 to engage sidewalls of the stepped bore and cam the implant therein to prevent further rotation. As with all prior embodiments, first tabs 170 and 172 also include camming surfaces 170a, 172a and second tabs 174, 176 include camming engaging surfaces 174a, 176a to engage edges of stepped bore and prevent expulsion of the implant after it has been rotated into position within the stepped bore.

Referring now to FIGS. 37-40, there is disclosed a further alternate embodiment of an intervertebral implant. Intervertebral implant 190 generally includes a cylindrical body portion 192 having a throughbore 194. Implant 190 includes first tabs 196 and 198 spaced a predetermined distance from first end 200 of cylindrical

5

body portion 192. Implant 190 additionally includes second tabs 202 and 204

10

positioned adjacent and spaced a distance from second end 206 of cylindrical body

portion 192. Implant 190 includes camming structure formed on the first and second

tabs which permits rotation of the implant in either direction upon installation.

15

5 Specifically, first tabs 196 includes opposed inclined camming surfaces 208a and 208b

and first tab 198 also includes opposed inclined camming 210a and 210b. Similarly,

second tab 202 includes opposed inclined camming surfaces 212a and 212b and second

20

tab 204 includes opposed inclined camming surfaces 214a and 214b. The opposed

inclined camming surfaces allow the implant to be rotated in either direction and still

25

10 achieve a camming function within a stepped bore. As with prior embodiments, first

tabs 196 and 198 include bore engaging surfaces 196a and 198a respectively.

Similarly, second tabs 202 and 204 include bore engaging surfaces 202a and 204a

30

respectively. Implant 190 may preferably be provided with an installation slot 216 and

a bore 218 extending between slot 216 and throughbore 194.

35

15 Referring now to FIGS. 41-44, there is disclosed a further alternate

embodiment of an intervertebral implant. Implant 220 generally includes cylindrical

body portion 222 having a throughbore tube 224 defined therein. First tabs 226 and

40

228 and second tabs 230 and 232 extend radially from cylindrical body portion 222.

The first and second tabs of implant 220 include threaded structure which allows the

20

implant to engage precut threads in a stepped bore formed between adjacent vertebrae

45

or to act as teeth to cut into bone and thereby secure implant 220 within a stepped bore

50

55

5 between adjacent vertebrae. Alternatively, the tabs may be grooved but not necessarily threaded. Specifically, first tab 226 includes a threaded surface 234 and first tab 228
10 includes a threaded surface 236. Similarly, second tab 230 includes a threaded surface 238 and second tab 232 includes a threaded surface 240. It should be noted that the
5 number of threads on any individual tab may differ from the number on an adjacent or
15 diametrically opposed tab. Preferably, an installation slot 242 is provided having a bore 244 extending between slot 242 and into throughbore 224.

20 Referring now to Figs. 45-48, there is disclosed an asymmetrical embodiment of an intervertebral implant. Implant 250 generally includes a cylindrical
10 body portion 252 having a first end 254 and a second end 256. A throughbore 258
25 extends through implant. A first tab 260 is provided a predetermined spaced distance from first end 254 and a second tab 262 is provided a predetermined spaced distance
30 from second end 256. As shown, first and second tabs 260, 262 are radially spaced approximately 180°. First and second tabs 260, 262 may be of any of the previously
15 described shapes in the prior embodiments and include respective camming and/or
35 abutment bone engaging surfaces. Additionally, implant 250 may be provided with an installation slot 269 and a bore 266 and be formed in accordance with the previously
40 described methods and of same or similar materials.

Referring now to Figs. 49-52, there is disclosed an intervertebral
20 implant 270 designed to utilize a plug, which may be formed from cortical bone, to
45 form the tabs. Implant 270 generally includes a cylindrical body portion 272 formed in

5 accordance with the above described method such that the medullary canal provides a
throughbore 274 in implant 270. A cortical plug 276 formed by turning on a lathe,
10 milling, or other appropriate machining process. Plug 276 is positioned within
throughbore 274 which may be suitably drilled or otherwise prepared to receive plug
5 276 such that first and second ends 278, 280 of cortical plug 276 extend radially
15 outward from body portion 272. First and second ends 278, 280 thus form tabs which,
when installed by the above described method, engage edges of a stepped bore formed
20 in adjacent vertebrae. An installation slot 282 may be formed in an end 284 of body
portion and a bore 286 extends between slot 282 and throughbore 274.

10 Referring now to Figs. 53-56, there is disclosed an alternate embodiment
25 of an intervertebral implant with a substantially shortened body portion. Implant 290 is
designed to be provided in various diameters such that two or more implants 290 of
30 differing diameters may be used together to introduce the appropriate lordosis into the
spine. Implant 290 generally is similar to the above described implants except that the
15 length of a cylindrical body portion 292 is substantially abbreviated or shortened.
35 Implant 290 may include any of the previously described versions of tabs and
preferably first and second tabs 294, 296. Implant 290 may also include an installation
40 slot 298 and bore 300 extending between slot 298 and end face 302 of body portion
292. However, it is not contemplated that implant 290 have a throughbore and thus
20 implant 290 may be formed from bone extending up to, but not including, the

5

medullary canal of a long bone. Further, various body portion configurations, such as, for example, tapered, semi-conical, etc. are also envisioned.

10

5

15

20

Referring now to Figs. 57-60, there is disclosed another embodiment of an intervertebral implant. Implant 310 generally includes a tapered cylindrical body portion 312 having a first end 314 and a second end 316. The diameter of first end 314 is smaller than the diameter of second end 316. Implant 310 may be formed by the disclosed method and include a throughbore 318, an installation slot 320 and a bore 322 extending from slot 320 to throughbore 318. Additionally, implant includes first tabs 324, 326 and second tabs 328, 330.

25

30

35

40

10

15

As best shown in FIGS. 61-63, various body portions other than cylindrical are within the contemplated scope of the present disclosure. These body portions may include a body portion 340, having a rectangular cross-section (FIG. 61), a body portion 350 having an oval cross-section (FIG. 62), a body portion 360 having a multi-sided cross-section (FIG. 63), etc. The embodiments disclosed in FIGS. 61-63 may obviously include structure similar or identical to that provided in previously described embodiments such as, for example, throughbores, installation slots, bore and all the various configurations and orientations of tabs.

45

50

20

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, differing or alternate tab constructions may be provided on a single implant. Additionally, the various configurations may be combined on individual tabs. Therefore, the above description should not be construed

55

5

as limiting, but merely as exemplifications of preferred embodiments. Those skilled in
the art will envision other modifications within the scope and spirit of the claims
appended hereto.

10

15

20

25

30

35

40

45

50

55

Claims

5

10

15

20

25

30

35

40

45

50

55

5

WHAT IS CLAIMED IS:

10

1. An intervertebral implant comprising:

a substantially cylindrical body portion having a first end and a second end; and

15

5 at least two tabs extending radially outward from the substantially cylindrical body portion, each of the at least two tabs being longitudinally displaced from the first and second ends.

20

2. An intervertebral implant according to claim 1, wherein the at least

two tabs include a first tab and a second tab, the first tab being radially spaced

25

10 approximately 180° about the substantially cylindrical body portion from the second tab.

30

3. An intervertebral implant according to claim 2, wherein the first tab

is longitudinally spaced along the substantially cylindrical body portion from the second tab.

35

15 4. An intervertebral implant according to claim 1, wherein the

substantially cylindrical body portion has a longitudinal axis and at least one

throughbore defined in the substantially cylindrical body portion, the throughbore

40

having a central axis which is substantially perpendicular to the longitudinal axis of the substantially cylindrical body portion.

45

20 5. An intervertebral implant according to claim 1, wherein said

substantially cylindrical body portion has a maximum diameter, and each tab of the at

50

55

5

least two tabs has a width less than or equal to the maximum diameter of the substantially cylindrical body portion.

10

6. An intervertebral implant according to claim 1, wherein said substantially cylindrical body portion defines an installation slot in one end thereof.

15

5

7. An intervertebral implant according to claim 4, wherein said substantially cylindrical body portion defines an installation slot in one end thereof and a bore extending between the slot and the throughbore.

20

8. An intervertebral implant according to claim 4, wherein the at least two tabs are radially spaced from the throughbore.

25

10

9. An intervertebral implant according to claim 1, wherein the at least two tabs include a pair of radially opposed first tabs and a pair of radially opposed second tabs.

30

10. An intervertebral implant according to claim 1, wherein each tab of the at least two tabs has a wedge-shaped surface.

35

15

11. An intervertebral implant according to claim 1, wherein each tab of the at least two tabs has a camming surface.

12. An intervertebral implant as claimed in claim 11, wherein each camming surface is flat.

40

13. An intervertebral implant as claimed in claim 11, wherein each camming surface includes opposed inclined camming surfaces.

45

50

55

5

14. An intervertebral implant according to claim 11, wherein each tab of the at least two tabs has a profile that defines a progressive camming surface.

10

15. An intervertebral implant according to claim 1, wherein each tab of the at least two tabs includes a threaded bone engaging surface.

15

5

16. An intervertebral implant according to claim 1, wherein the substantially cylindrical body portion defines a throughbore and each tab of the at least two tabs is an end of a plug positioned through the throughbore.

20

17. An intervertebral implant according to claim 1, wherein the substantially cylindrical body portion is tapered.

25

10

18. The intervertebral implant according to claim 1, wherein the implant is formed from a biocompatible material.

30

19. The intervertebral implant according to claim 18, wherein the implant is formed of bone.

35

15

20. The intervertebral implant according to claim 19, wherein the bone is animal bone.

21. The intervertebral implant according to claim 19, wherein the bone is human.

40

22. The intervertebral implant according to claim 19, wherein the bone is surface demineralized.

45

20

23. A method of installing an intervertebral implant between adjacent vertebrae comprising the steps of:

50

55

5

providing an intervertebral implant having a substantially cylindrical body portion and at least two tabs extending radially from the body portion;

10

forming a stepped bore in a portion of two adjacent vertebrae, the stepped bore having an enlarged diameter area and a reduced diameter area;

15

5 aligning the at least two tabs with a space defined between the adjacent vertebrae;

20

inserting the implant into the space a sufficient distance such that the at least two tabs are positioned adjacent the enlarged diameter area of the bore; and rotating the implant to position the tabs within the enlarged diameter area

25

10 of the bore.

24. An intervertebral implant comprising:

a body portion having a first end and a second end; and

30

at least two tabs extending radially outward from the body portion, each of the at least two tabs being longitudinally displaced from the first and second ends.

35

15 25. The intervertebral implant according to claim 24, wherein the body portion has a substantially rectangular cross-section.

40

26. The intervertebral implant according to claim 24, wherein the body portion has a substantially oval cross-section.

45

20 27. The intervertebral implant according to claim 24, wherein the body portion has a substantially multi-sided cross-section.

50

55

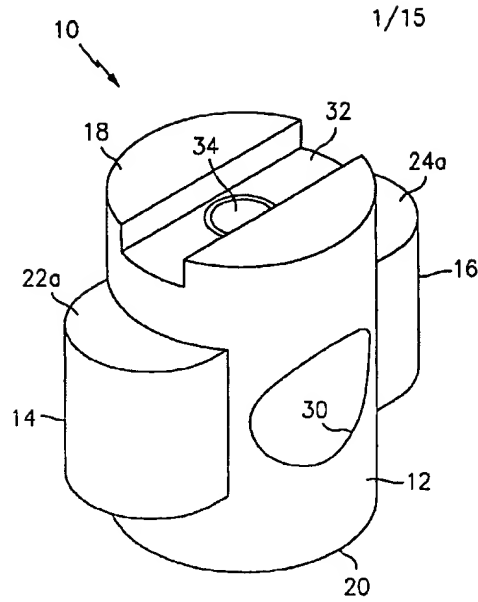


FIG. 1

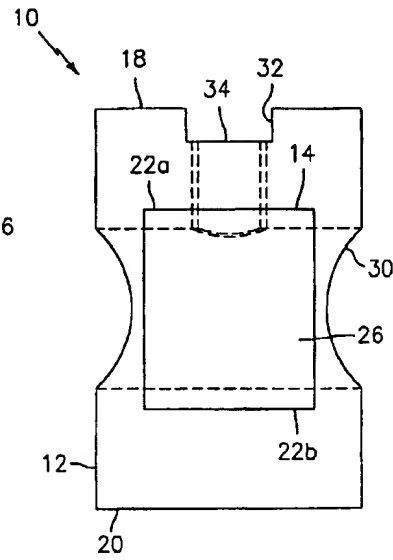


FIG. 2

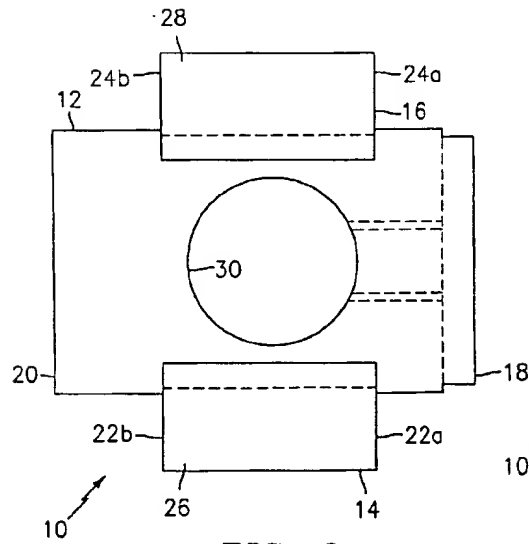


FIG. 3

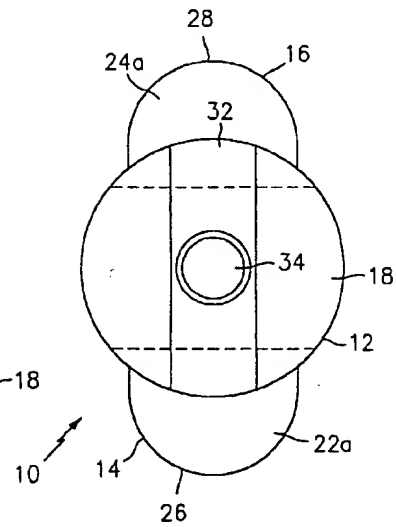


FIG. 4

2/15

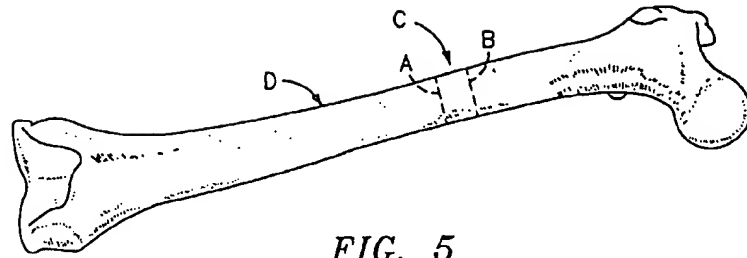


FIG. 5

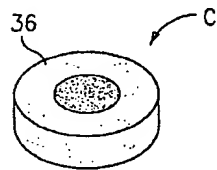


FIG. 6

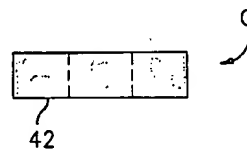


FIG. 7

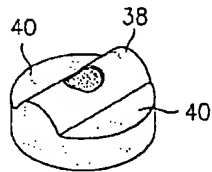


FIG. 8

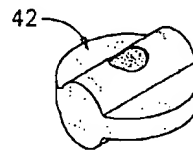


FIG. 9

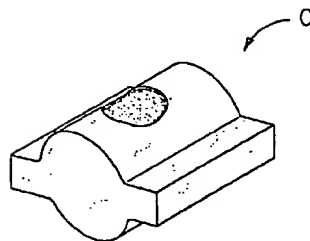


FIG. 10

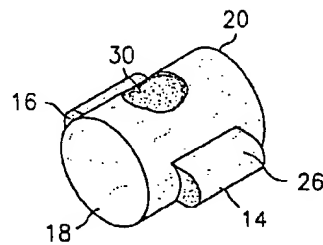


FIG. 11

3/15

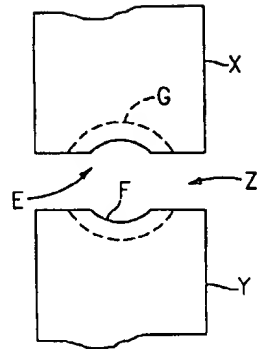


FIG. 12

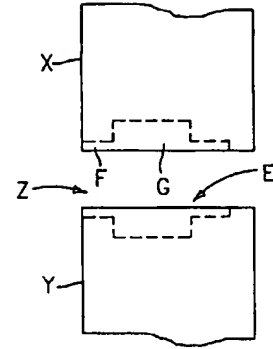


FIG. 13

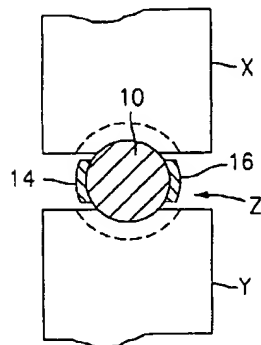


FIG. 14

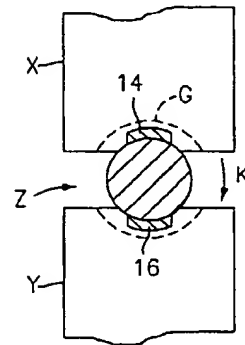


FIG. 15

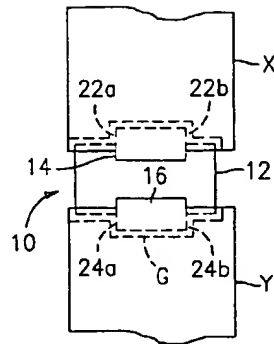


FIG. 16

SUBSTITUTE SHEET (RULE 26)

4/15

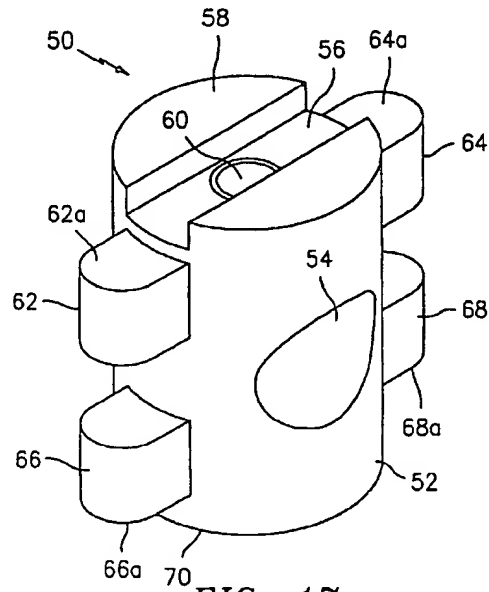


FIG. 17

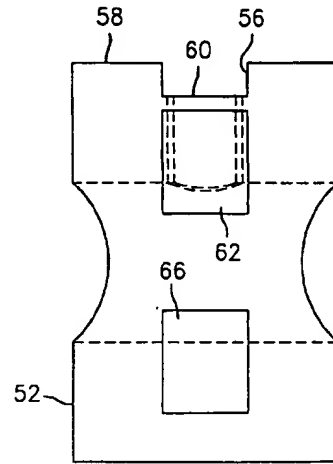


FIG. 18

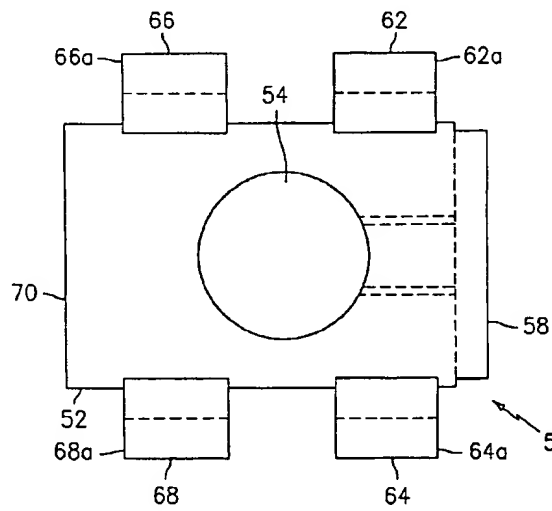


FIG. 19

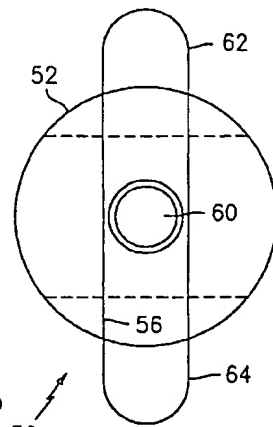


FIG. 20

5/15

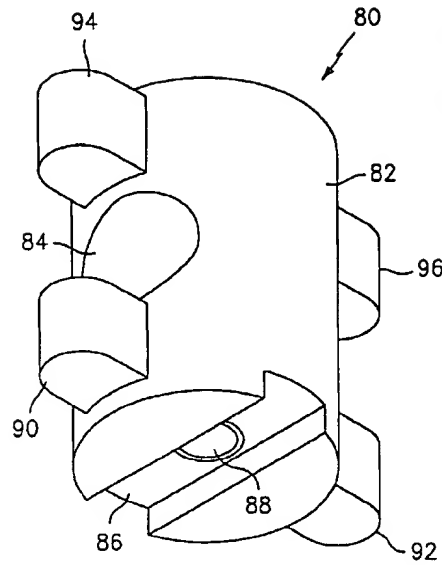


FIG. 21

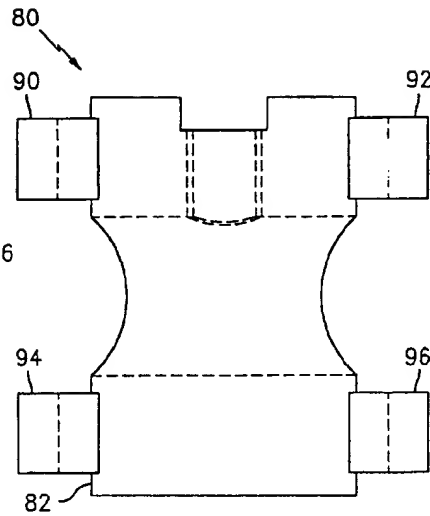


FIG. 22

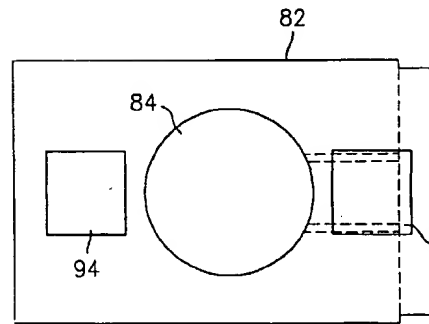


FIG. 23

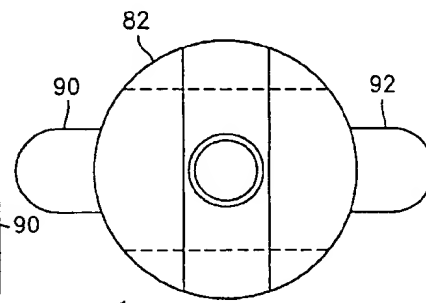


FIG. 24

6/15

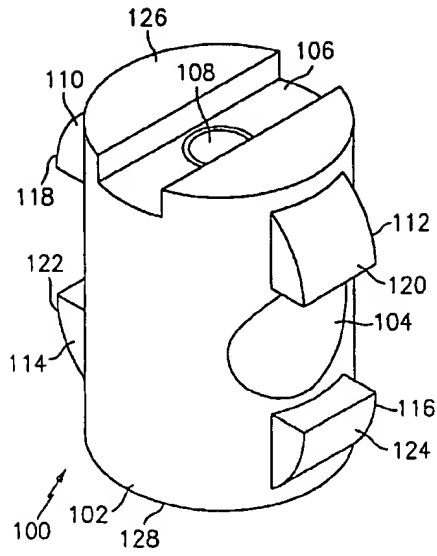


FIG. 25

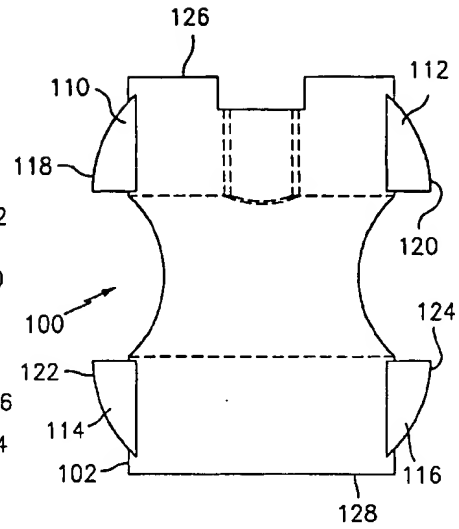


FIG. 26

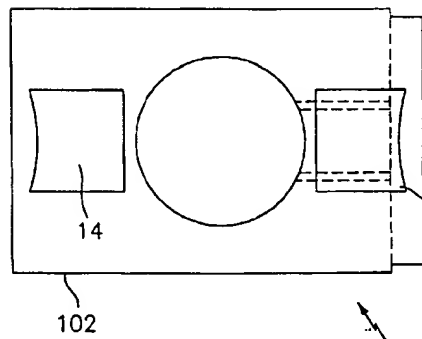


FIG. 27

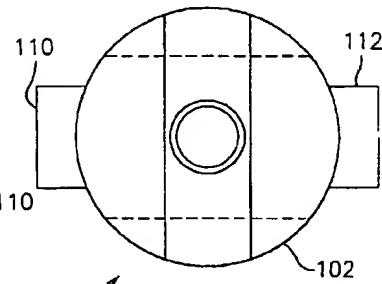


FIG. 28

7/15

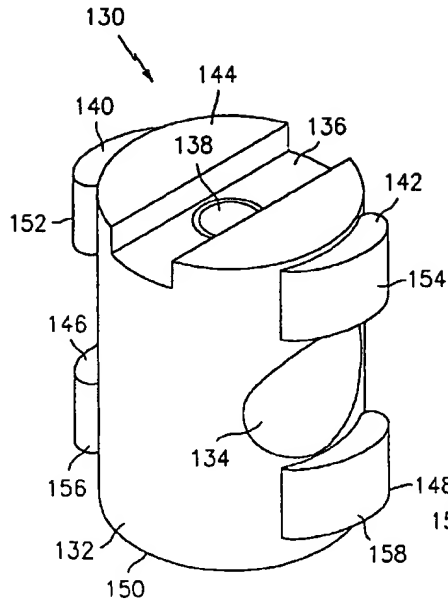


FIG. 29

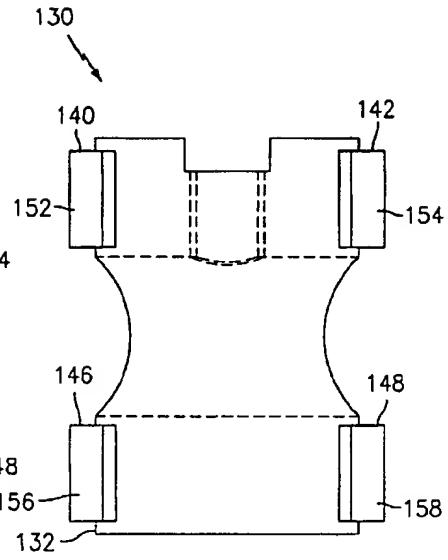


FIG. 30

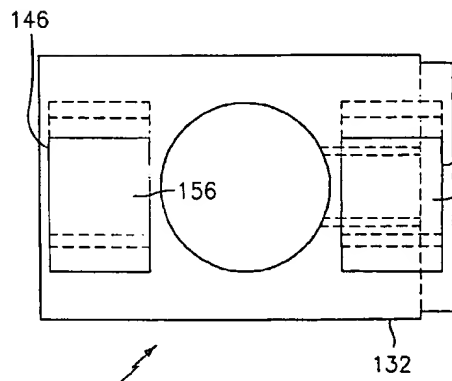


FIG. 31

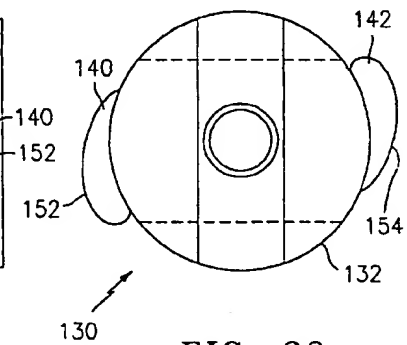


FIG. 32

8/15

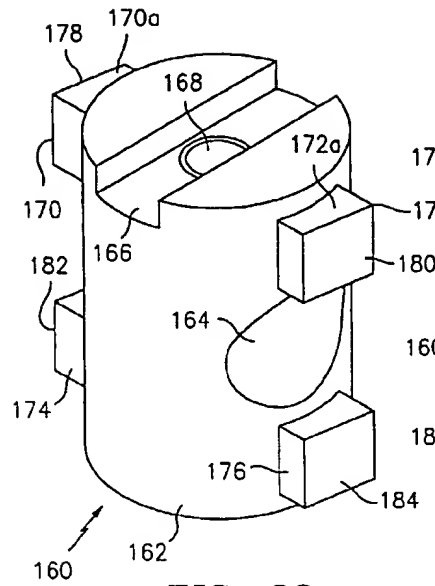


FIG. 33

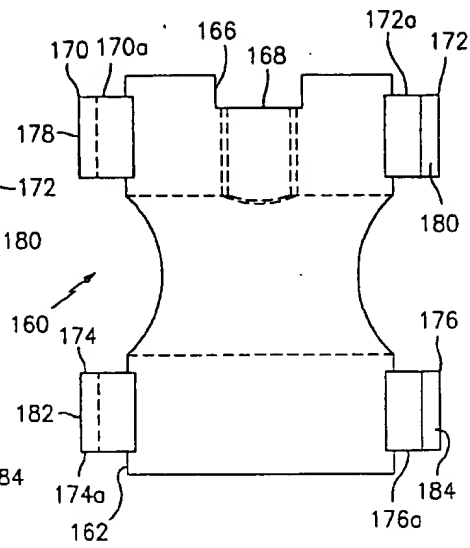


FIG. 34

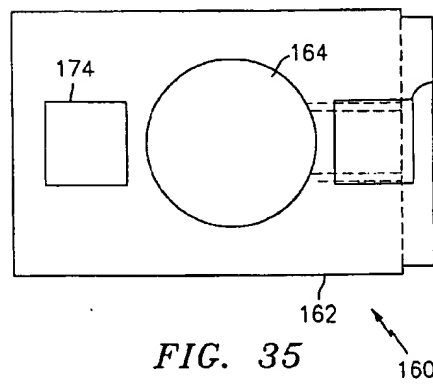


FIG. 35

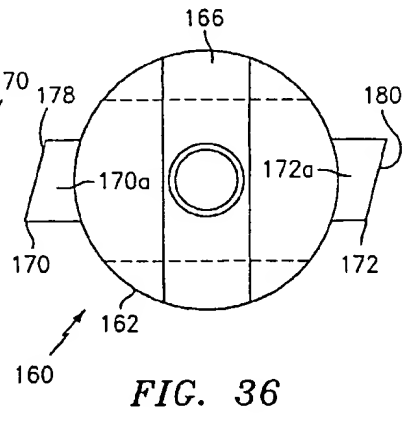


FIG. 36

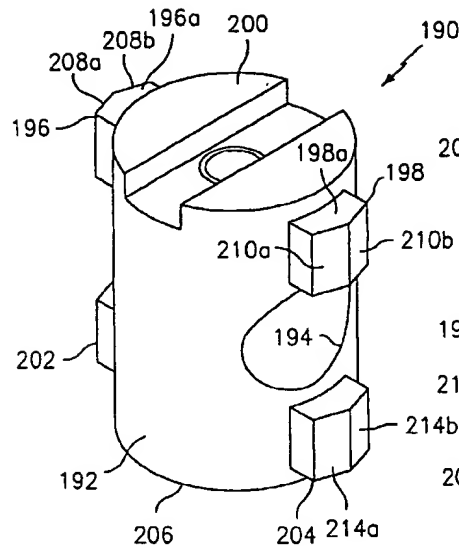


FIG. 37

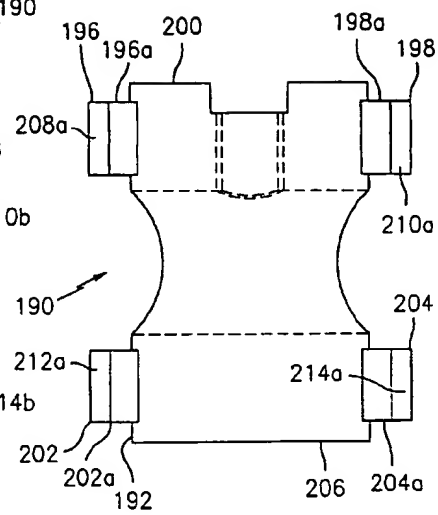


FIG. 38

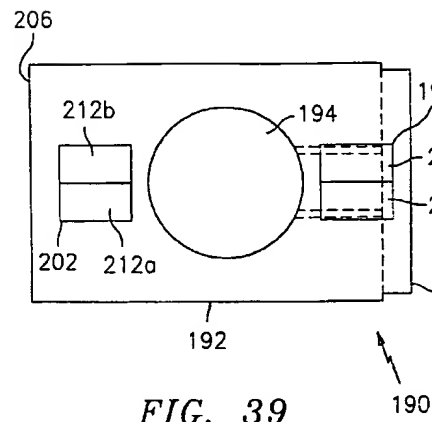


FIG. 39

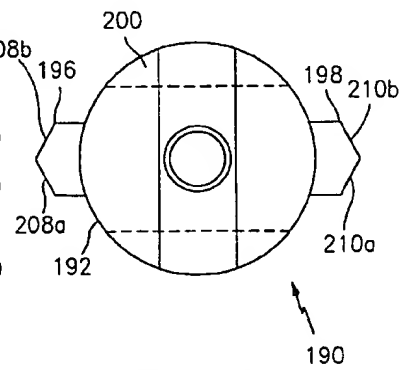


FIG. 40

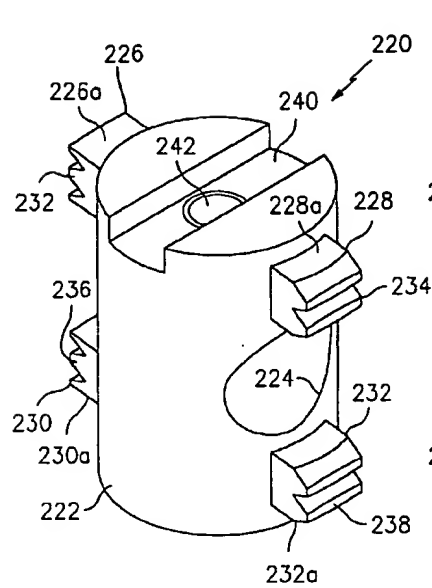


FIG. 41

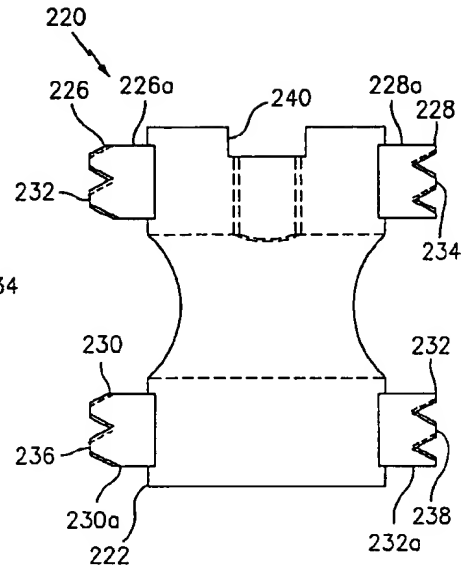


FIG. 42

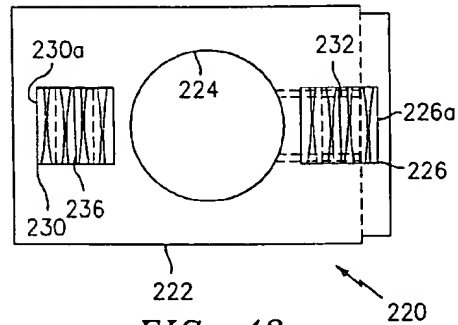


FIG. 43

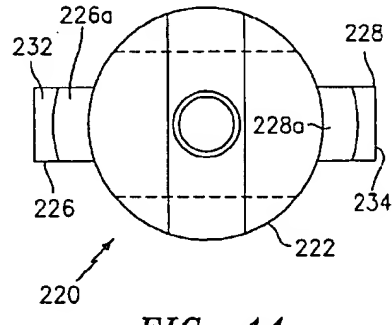


FIG. 44

11/15

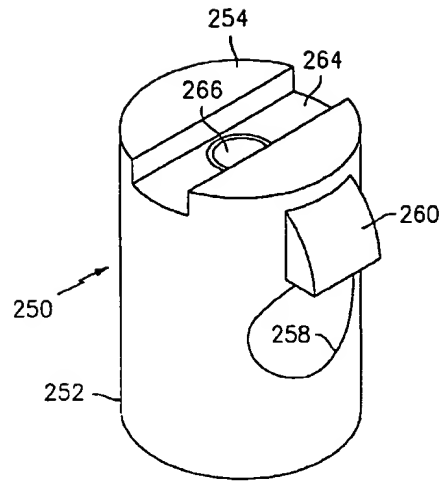


FIG. 45

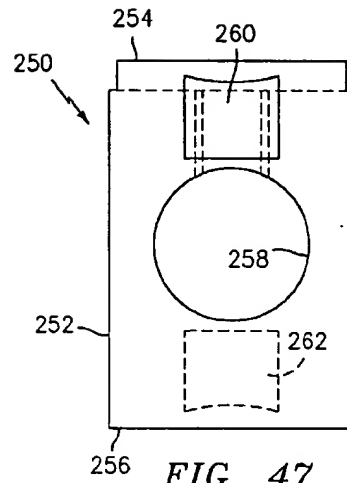


FIG. 47

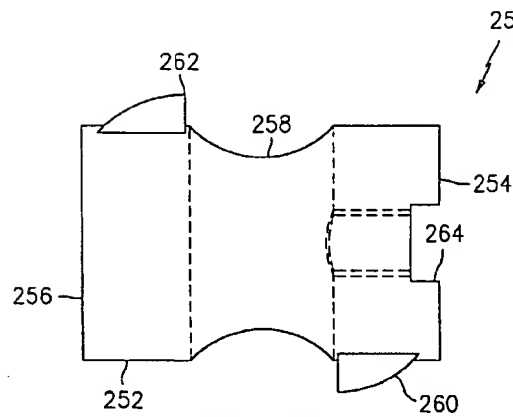


FIG. 46

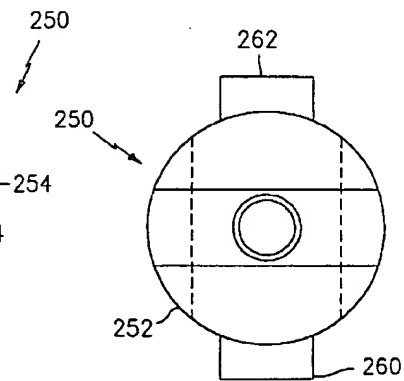


FIG. 48

12/15

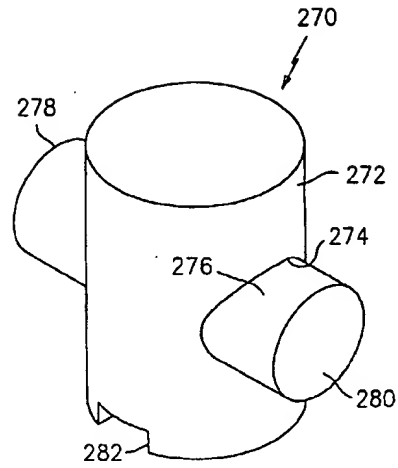


FIG. 49

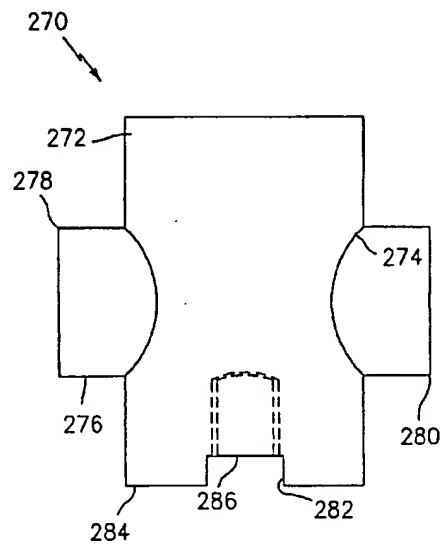


FIG. 50

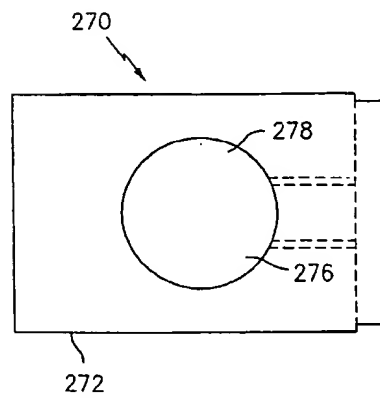


FIG. 51

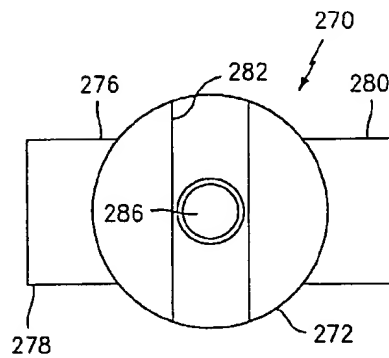
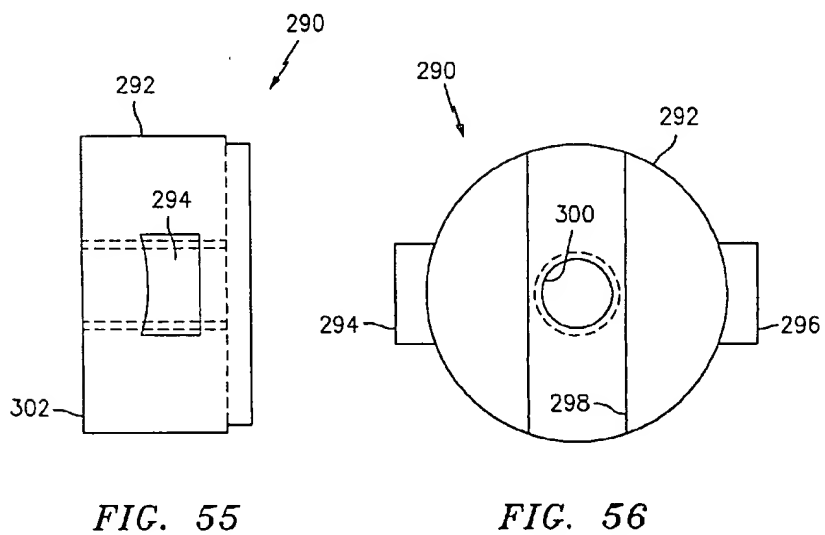
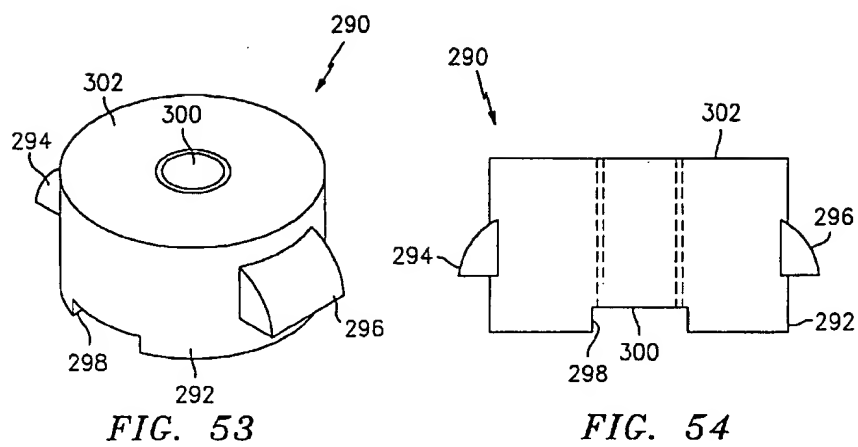


FIG. 52



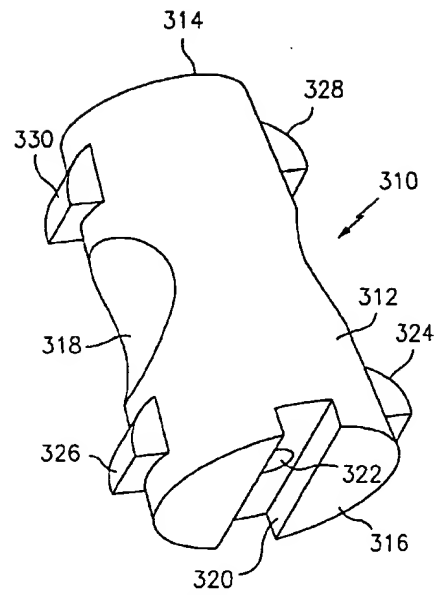


FIG. 57

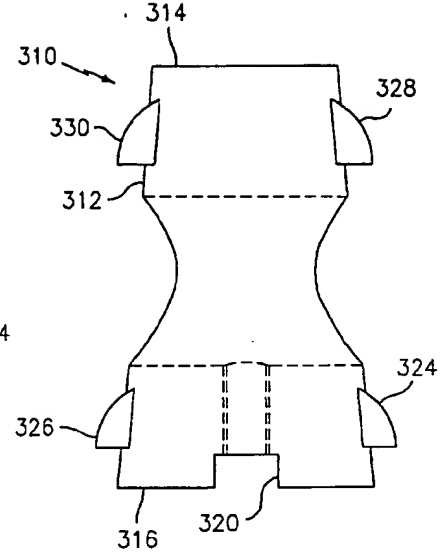


FIG. 58

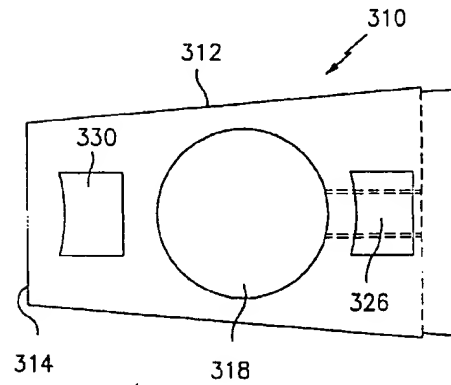


FIG. 59

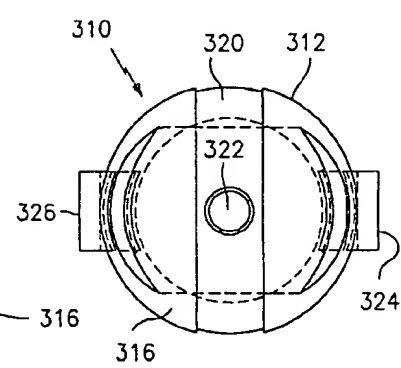


FIG. 60

15/15

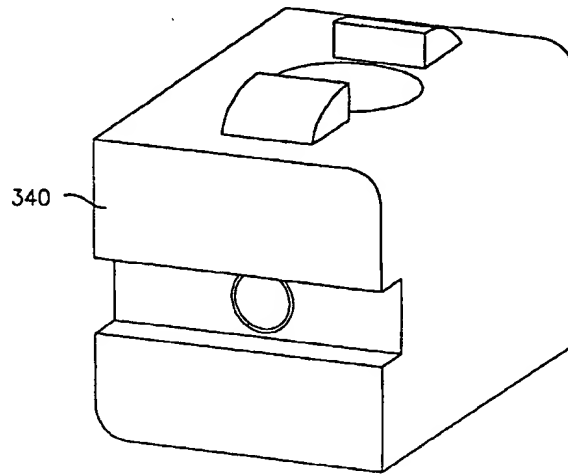


FIG. 61

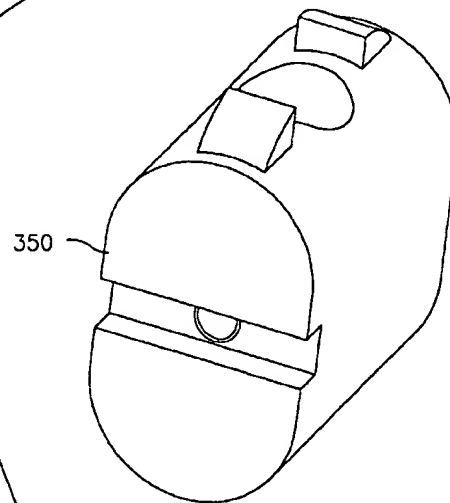


FIG. 62

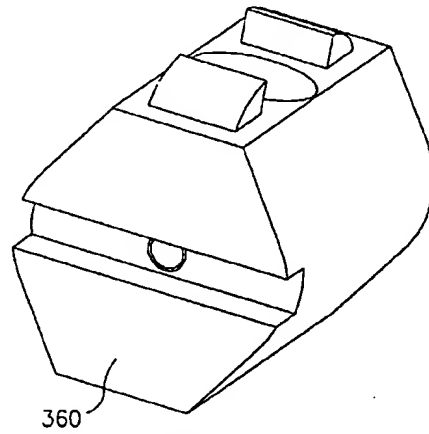


FIG. 63

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/15654

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61F 2/44 US CL : 623/17.11 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 623/16.11, 17.11, 17.16 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WEST Search Terms: tabs, pegs, vertebrae, implant, prosthesis, cylindrical		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,593,409 A (MICHELSON) 14 January 1997, col. 8 lines 58-66, col. 10 lines 33-39, and Figs. 11, 12, 22, 28, 29.	1, 4-8, 10-14, 18-21, 24, 26, 27 ----- 16, 22, 25
X	US 5,458,638 A (KUSLICH et al.) 17 October 1995, col. 3 lines 35-40, 66, 67; col. 5 lines 33-38; col. 6 lines 47-61; and Figs. 1, 2A, 6, 14, and 16.	1-4, 9-15, 17, 18, 23, 24, 26
Y	US 5,899,939 A (BOYCE et al.) 04 May 1999, col. 3 lines 44-47, col. 4 lines 45-47, and col. 5 lines 14-15, 62-67.	22
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents.	"J" Later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	
"A" document defining the general state of the art which is not considered to be of particular relevance	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	
"E" earlier document published on or after the international filing date	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"A" document member of the same patent family	
"O" document referring to an oral disclosure, use, exhibition or other means		
"P" document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search 16 JULY 2000	Date of mailing of the international search report 21 AUG 2000	
Name and mailing address of the ISA/L'S Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer BRIAN PELLEGRINO	
Facsimile No. (703) 305-3230	Telephone No. (703) 306-5899	

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/15654

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,800,550 A (SERTICH) 01 September 1998, col. 5 lines 37-41, col. 6 lines 9-10, and Figs. 1A, 2.	16, 25